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NATIONAL INSTITUTES OF HEALTH
OFFICE OF TECHNOLOGY TRANSFER
6011 EXECUTIVE BLVD SUITE 325
ROCKVILLE, MD 20852-3804

EXAMINER

CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application. This application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid. Applicant's submission filed on August 26, 2005 has been entered. Claims 1-74 are pending. Claims 31-45 remain withdrawn from consideration, being drawn to non-elected subject matter. Claims 56 and 57 are rejoined with the elected invention. Claims 1-30 and 46-74 are under examination.
2. The rejection of claims 1-30 and 46-55 under 35 U.S.C. 103(a) as being unpatentable over Belshe *et al* (US Patent 5,869,036) in view of Collins *et al* (US Patent 6,264,957) and Klein *et al* (WO93/14207) is withdrawn in view of Applicant's arguments. Collins is not available as prior art because it was commonly owned with the instant invention at the time of filing.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 13 and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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It is apparent that rPIV3-2TM, rPIV3-2TM_{cp45}, rPIV3-2CT and rPIV3-2CT_{cp45} are required to practice the claimed invention because they are a necessary limitation for the success of the invention as stated in the claims. As a required element they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the viral constructs. See 37 CFR 1.802. One cannot practice the claimed invention without access to those particular viruses. The specification does not provide a repeatable method for obtaining exactly those constructs without access to rPIV3-2TM, rPIV3-2TM_{cp45}, rPIV3-2CT and rPIV3-2CT_{cp45} and they do not appear to be readily available material.

Deposit of rPIV3-2TM, rPIV3-2TM_{cp45}, rPIV3-2CT and rPIV3-2CT_{cp45} in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112., because the strains would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

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If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

4. Claims 26 and 71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to chimeric viruses, specifically wherein the substitution

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mutation at position 456 of the L protein is “to another amino acid”. The breadth of the claims has not been adequately described such that one of skill in the art would know how to practice the invention.

The specification describes a mutation wherein the amino acid at position 456 of PIV3 is changed to leucine. However, Applicant’s claims encompass a substitution of any of the 20 amino acids. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is one example (456 F) out of 20 possibilities and no particular function. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of

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the invention and reference to a potential method of isolating it. The compound itself is required.

See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai*

Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10, 12, 19-23, 25, 28-30, 46-49, 53-59, 65, 66 and 77-74 are rejected under 35 U.S.C. 102(e) as being anticipated by Belshe *et al.* (US 5,869,036, “Belshe”). The summary of claims and teachings of Belshe are of record. With regard to the new claims, their subject matter is directed to the same subject matter previously claimed.

The claims are directed to infectious chimeric PIVs having a human PIV background genome and a chimeric glycoprotein from another antigenically distinct HPIV. Belshe teaches hybrid viruses having glycoproteins exchanged between HPIV1, HPIV2 and HPIV3 (as a background genome), see abstract and Example 7).

Response to Arguments

6. Applicant’s arguments and observations are primarily directed to the following:

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- Applicant discloses that the recovery of Belshe's hybrid *cp45* viruses was performed by a complementation assay wherein a plasmid expressing wild-type HPIV3 L protein provided a very small degree of recovery of virus plaques.
 - In response to this observation, the examiner agrees that the viruses were recovered. Regardless of the amount recovered, Belshe did recover virus (col. 8, lines 21-25). The claims do not require a particular amount of virus be produced.
- Applicant argues that Belshe only uses the HPIV *cp45* genome or antigenome, having at least two of the three defined point mutation in the L protein to obtain an attenuated HPIV3 virus. Applicant notes that Belshe suggests that an attenuated HPIV3 virus might be modified by substitution of its genes encoding the HN and/or F glycoproteins with the corresponding genes from a target virus, among those listed in col. 8, lines 42-58. Applicant asserts that the method with which to accomplish this suggestion by Belshe is not disclosed whatsoever.
 - The complex method to which Applicant is referring to is not present in the claims. Belshe's method of producing viruses is the same as that instantly claimed: cell culture. The method steps of the instant claims include expressing the polynucleotide genome in a cell culture. Belshe teaches the same method (col. 8, lines 21-25).
- Applicant argues that the claims now recite that the chimeric genome comprises portions of the glycoproteins of different PIVs that are joined. Applicant asserts that this embodiment is distinguished over Belshe because Belshe teaches the exchange of HN or F genes between the two strains.

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- In response to this argument, the claims do not recite limitations that distinguish over Belshe with regard to joining segments together. The claim language is broad enough to be encompassed by Belshe's teachings.
- Applicant points out that Belshe's disclosure regarding hybrid *cp45* viruses is limited to Example 7, and the mention of exchanging heterologous surface glycoproteins for those on the PIV genome.
 - In response to this observation, the specification describes a method of making the virus using the *cp45* virus genome as a background genome into which other genes may be inserted (co. 9-10).
- Applicant points out that Belshe's explanation for attenuation is mutation of the L protein, not the wild-type. Applicant asserts that Belshe does not contemplate any attenuated virus obtained by mutating other than the L protein. In contrast, Applicant's claims are directed to embodiments wherein the L protein is the wild-type, and the virus remains attenuated due to other temperature-sensitive mutations.
 - In response to this observation, Example 5 of the Belshe patent discloses the introduction of the wild type L gene into the *cp45* genome. Belshe recovered virus that contained a wild type L gene and also contained mutation in gene other than the L gene. Because the *cp45* genome necessarily contains mutations in other genes besides the L gene, the introduction of the wild type L gene resulted in a virus that expressed the wild type L protein along with the other mutations that are naturally present in the *cp45* virus (col. 8, lines 21-25).

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- Applicant argues that claims 59-74 should not be rejected over Belshe because Belshe does not teach the insertion of genes in the recited positions.
 - In response to this argument, insertion of a heterologous HN protein from HPIV2 into HPIV3, for example, would occur between HN and L open reading frames.

The claim limitations do not limit the insertion site such that it is distinguished over Belshe.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-30 and 46-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 144-215 of copending Application No. 09/083,793. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because the subject matter of the copending application is encompasses the embodiments set forth in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-30 and 46-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 53-85 of copending Application No. 09/458,813. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the copending application is encompasses the embodiments set forth in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-30 and 46-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 84-163 of copending Application No. 09/586,479. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the copending application is encompasses the embodiments set forth in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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10. Claims 1-30 and 46-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 180-222 of copending Application No. 09/733,692. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the copending application is a species of the instantly claimed genus of PIVs, rendering the genus claims obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

11. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen
November 10, 2005